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| 10/647,174 | 08/25/2003 | Zheng Zhang | 571-872 | 1507 |
| 1059 | 7590 | 04/07/2005 | EXAMINER | |
| BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA | | | PENG, KUO LIANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1712 | |

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,174

Applicant(s)

ZHANG ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/4/04 IDS.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☒ Claim(s) 1-40, 46, 53 and 57-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following Office action is based on the term “polyol silane precursor” in the claims being a polyol silane precursor to be hydrolyzed/condensed to a siliceous material.

Double Patenting

2. A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-60 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-60 of copending Application No. 10/814,123.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Objections

4. Claims 1-40 and 49-53 are objected to because of the following informalities:

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In Claim 1 (line 9), Claim 39 (line 7) and Claim 49 (line 9), should “R¹, R² and R³” be -- OR¹, OR² and OR³ --?

In Claim 29 (line 1), should “s” be -- is --?

In Claim 30 (line 1), should “he” be -- the --?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1 (line 9), Claim 39 (line 7) and Claim 49 (line 9), “may be” causes confusion because it is not clear as to whether the recited groups are hydrolysable or non-hydrolysable.

In Claim 41 (lines 4-6 and 8-10), Claim 54 (lines 4-6 and 8-10), Claim 56 (lines 4-6 and 8-10) and Claim 57 (lines 6-8 and 10-12) and Claim 58 (line 3-5), it is not clear as to what OR¹, OR² and OR³ refer to.

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In Claim 41 (lines 8-10), Claim 42 (line 3), Claim 54 (lines 7-9), Claim 56 (lines 7-9), Claim 57 (lines 9-11) and Claim 58 (line 4), it is not clear as to what n refers to.

Claim 51 recites the limitation "whose reaction" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitation "the anionic charge" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claims 59 and 61 recite the limitation "the anionic charge" in Claim 59 (line 3). There is insufficient antecedent basis for this limitation in the claim.

Regarding Claims 59 (line 4) and 61 (line 3), the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 61 provides for the use of a column, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 61 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the

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respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

10. Claims 1-60 are rejected under 35 U.S.C. 102(g) as being anticipated by Zhang123 (US 10/814,123).

The invention of the instant claims is fully encompassed by that of Claims 1-60 of Zhang123. It is noted that the assignment data of both Zhang123 and the present application have not been available yet.

11. Claims 40, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill2001 (Chem. Mater. (2001), 13, pages 3404-3421).

For Claims 40 and 50, Gill2001 discloses a siliceous material prepared by hydrolysis/condensation of a poly(glyceryl silicate) in the presence of water-soluble polymers to form an interpenetrating polymer network. The resulted material can be used for bio-doping. (page 3407 and pages 3410-3411 and Figure 1) Gill2001 uses the poly(glyceryl silicate) which is an intermediate when Applicants' polyol silane precursor is partially hydrolyzed/condensed. However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

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method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). For Claim 48, as mentioned previously, Gill2001’s siliceous material prepared by hydrolyzing/condensing the poly(glyceryl silicate) in the presence of water-soluble polymers. Note that the poly(glyceryl silicate) is actually an intermediate when Applicants’ polyol silane precursor is partially hydrolyzed/condensed. Furthermore, Gill2001 teaches the use of water-soluble polymers such as poly(ethylene glycol), poly(vinyl alcohol)(a polyalcohol), etc. (page 3410, left column) that are used by Applicants too (Specification, page 20, last paragraph). Therefore, Examiner has a reasonable basis to believe that both final products should have the same morphology, i.e., bimodal meso/macroporous silica monolith.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-5, 8, 9-10, 38, 40-45 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi688 (US 5 009 688) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598).

For Claims 1-5, 8 and 40, Nakanishi688 discloses a method of preparing siliceous materials by hydrolyse/condense a silicone alkoxide in the presence of a water-soluble organic polymer such as polyethylene oxide, etc. undergoing phase separation. (col. 2, lines 7-43 and Examples) Nakanishi688 is silent on the use of polyol silane precursor. However, Gill teaches that by replacing the alkoxysilyl group wherein the alkoxy is a residue of a monool such as methanol, ethanol with an alkoxysilyl group wherein the alkoxy is a residue of a polyol such as glycerol, the resulting sol-gel material possesses far better properties. (Abstract)

Furthermore, during hydrolysis, polyol such as glycerol is liberated, which is less deleterious to bioactivity of the siliceous materials. It also causes less shrinkages and less pore collapse as compared to the typical silicone alkoxide such as silicone methoxide or silicone ethoxide during xerogel formation. (page 8588, left column, 2nd paragraph) In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a silicone glyceryloxide

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in Nakanishi688's method. Especially, Gill is in the same field as that of Nakanishi688's endeavor. For Claims 9-10, the molecular weight and the concentration of the polyethylene oxide are exemplified in Examples 3-1 to Examples 3-4. For Claim 38, the reaction solution contains 1N nitric acid. (Examples 3-1 to Examples 3-4) As such, the pH of the solution should be 3, which reads on the pH of about 4. For the pH range of from 4 to 11.5, Nakanishi688 further teaches in Examples 3-1 to 3-4 that the concentration of the nitric acid can be changed for controlling pore size. In other words, the pH is a Result-Effective variable. Therefore, it would have been obvious to one of ordinary skilled in the art at the time of the invention was made to adjust the pH to whatever value through routine experimentation in order to obtain a product with a desired pore size. Especially, Applicants do not show the criticality of the pH range. See MPEP 2144.05 (II). For Claims 41-45 and 47-48, since Nakanishi688 in view of Gill's process is substantially the same as that in the present invention, Examiner has a reasonable basis to believe that both products obtained should be a bimodal meso/macroporous silica monolithic silica material. Note that the language in Claims 42-44 does not limit the additive being a compound of Formula I.

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14. Claims 1-5, 8-10, 40-45, 47-52, 54-55 and 56 are rejected under 35

U.S.C. 103(a) as being unpatentable over Nakanishi875 (US 5 624 875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598).

For Claims 1-5, 8-9, 40, 49-52, 54-55 and 56, Nakanishi875 discloses a method for producing chromatography column, (bio)sensor, (bio)reactor by hydrolyse/condense a silicone alkoxide such as tetramethoxysilane in the presence of a water soluble polymer such as poly(ethylene oxide), etc. undergoing phase separation. (col. 3, lines 12-45, col. 4, lines 3-47, col. 5, lines 42-63, col. 6, lines 22-36 and Examples) Nakanishi875 is silent on the use of polyol silane precursor. However, Gill teaches that by replacing the alkoxysilyl group wherein the alkoxy is a residue of a monool such as methanol, ethanol with an alkoxysilyl group wherein the alkoxy is a residue of a polyol such as glycerol, the resulting sol-gel material possesses far better properties. (Abstract) Furthermore, during hydrolysis, polyol such as glycerol is liberated, which is less deleterious to bioactivity of the siliceous materials. It also causes less shrinkages and less pore collapse as compared to the typical silicone alkoxide such as silicone methoxide or silicone ethoxide during xerogel formation. (page 8588, left column, 2nd paragraph) In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a silicone glyceryloxide in Nakanishi875's

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method. Especially, Gill is in the same field as that of Nakanishi875's endeavor, and Nakanishi875 recognizes the importance of the pore size control (col. 5, line 64 to col. 6, line 15). The molecular weight of poly(ethylene oxide) is exemplified in Examples 1-2. For Claim 10, Nakanishi875 is silent on the specific concentration of the poly(ethylene oxide). However, Nakanishi875 teaches that the concentration of the water soluble can affect the pore size. (col. 7, lines 31-45) In other words, the concentration of the poly(ethylene oxide) is a Result-Effective variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize the poly(ethylene oxide) in whatever amount through routine experimentation in order to obtain a desired pore size. Especially, Applicants do not show the criticality of the concentration. See MPEP 2144.05 (II). For Claims 41-45 and 47-48, since Nakanishi875 in view of Gill's process is substantially the same as that in the present invention, Examiner has a reasonable basis to believe that both products obtained should be a bimodal meso/macroporous silica monolithic silica material. Note that the language in Claims 42-44 does not limit the additive being a compound of Formula I.

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15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi875 (US 5 624 875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) and as evidenced by Barkin (US 3 374 103).

Nakanishi875 discloses a method for producing chromatography column by hydrolyse/condense a silicone alkoxide such as tetramethoxysilane in the presence of a water soluble polymer such as poly(ethylene oxide), etc. undergoing phase separation, *supra*, which is incorporated herein by reference. Nakanishi875 further discloses that the hydrolysis/condensation is carried out in a 0.001 mol/l aqueous solution of acetic acid. Barkin teaches the pKa of acetic acid is 4.76. Therefore, the pH of the reaction medium should fall within the range claimed in the present invention.

16. Claims 6-7, 11-37, 46, 53, 58-61 would be allowable if rewritten to overcome the claim objection, double patenting rejection and/or the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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17. Claims 39 and 57 would be allowable if rewritten or amended to overcome the claim objection and/or double patenting rejection, set forth in this Office action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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klp

April 1, 2005

A handwritten signature in black ink, appearing to read 'Kuo-Liang Peng', written in a cursive style.

Kuo-Liang Peng
Primary Examiner
Art Unit 1712